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AMENDMENT AND RESPONSE TO OFFICE ACTION**Remarks**

Claim 1-94 and 116-124 are canceled. New claims 128-135 are added. Support for claims 128-133 is found, for example, on page 5, line 23 to page 6, lines 17. Support for claims 134 and 135 is found, for example, on page 20, lines 8-17.

Rejection Under 35 U.S.C. § 112, second paragraph

Claims 68, 71, 82, 86, 95, 109, and 120 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. Applicants respectfully traverse this rejection to the extent that it is applied to the claims as amended.

The Examiner alleges that the phrase "greater than about" in claims 68, 82, and 95 renders the claims indefinite. Claims 68 and 82 are canceled. Claim 95 is amended to recite a blown or cast free-standing film comprising a polyhydroxyalkanoate (PHA), wherein the PHA has a molecular weight greater than 456,000 and wherein the film is made by melting a pellet composition comprising the PHA and a thermal stabilizer. Support for the amendment is found, for example, on pages 35-37, Examples 17-20.

The Examiner alleges that the conjunction "or" is in the wrong place in claims 71, 86, 109 and 120 and thus renders the claims indefinite. Claims 71, 86, and 120 are canceled. Claim 109 is amended to properly recite a Markush group.

Rejection Under 35 U.S.C. § 102

Claims 66, 78-80, 102, 104, 105 and 116 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,217,803 to McBride ("McBride") or U.S. Patent No. 5,300,576

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to Nemphos ("Nemphos"). Claims 66, 78-80, 83, 89, 94, 102, 104, 105, 116, 123 and 124 were rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 5,753,782 to Hammond *et al.* ("Hammond"). Applicants respectfully traverse this rejection to the extent that it is applied to the claims as amended.

The Legal Standard

For a rejection of claims to be properly founded under 35 U.S.C. § 102, it must be established that a prior art reference discloses each and every element of the claims. Hybritech Inc. v Monoclonal Antibodies Inc., 231 USPQ 81 (Fed. Cir. 1986), cert. denied, 480 US 947 (1987); Scripps Clinic & Research Found v. Genentech Inc., 18 USPQ2d 1001 (Fed. Cir. 1991). The Federal Circuit held in Scripps, 18 USPQ2d at 1010:

Invalidity for anticipation requires that all of the elements and limitations of the claim are found within a single prior art reference. . . There must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention. (Emphasis added)

A reference that fails to disclose even one limitation will not be found to anticipate, even if the missing limitation could be discoverable through further experimentation. As the Federal Circuit held in Scripps, Id.:

[A] finding of anticipation requires that all aspects of the claimed invention were already described in a single reference: a finding that is not supportable if it is necessary to prove facts beyond those disclosed in the reference in order to meet the claim limitations. The

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role of extrinsic evidence is to educate the decision-maker to what the reference meant to persons of ordinary skill in the field of the invention, not to fill in the gaps in the reference.

For a prior art reference to anticipate a claim, it must enable a person skilled in the art to practice the invention. The Federal Circuit held that "a §102(b) reference must sufficiently describe the claimed invention to have placed the public in possession of it. . . [E]ven if the claimed invention is disclosed in a printed publication, that disclosure will not suffice as prior art if it was not enabling." *Paperless Accounting Inc v Bay Area Rapid Transit Sys.*, 231 USPQ 649, 653 (Fed. Cir. 1986).

Claims 66-94, 116, 123 and 124 are canceled. Claims 102, 104, and 105 are amended to recite a method of producing a blown or cast *free-standing* film comprising melting a pellet composition comprising a PHA and a thermal stabilizer, wherein the PHA in the film has a molecular weight greater than 456,000.

a. U.S. Patent No. 5,217,803 to McBride et al.

Claims 102, 104, and 105 are directed to a method of producing a blown or cast *free-standing* film comprising melting a pellet composition comprising a PHA and a thermal stabilizer, wherein the PHA in the film has a molecular weight greater than 456,000. McBride describes biodegradable films that comprise a blend of an interpenetrated network of destructure starch with ethylene/acrylic acid copolymers or ethylene/vinyl alcohol copolymers, and an aliphatic polyester such as polycaprolactone. In a preferred embodiment, the

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aliphatic polyester is polycaprolactone with an initial molecular weight of about 80,000 grams/mole (col. 5, lines 37-39). McBride does not disclose a method of producing blown or cast free-standing films comprising melting a composition comprising a PHA and a thermal stabilizer, wherein the PHA in the film has a molecular weight greater than 456,000. In fact, McBride is silent regarding the molecular weight of the PHA in the film. Therefore, the claims, as amended, are novel over McBride.

b. U.S. Patent No. 5,300,576 to Nemphos et al.

Nemphos describes polymer blends having a T_g of not less than 62°C, comprising a polyhydroxyalkanoate having a molecular weight greater than 40,000 and one or more polymers having a T_g from 75°C to 200°C (col. 2, lines 28-50). Suitable PHAs are described at col. 3, lines 3-16). Nemphos does not disclose a method of producing *blown or cast free-standing films* comprising melting a composition comprising a PHA and a thermal stabilizer, wherein the PHA in the film has a molecular weight greater than 456,000. In fact, Nemphos does not disclose or even suggest a method of making PHA films. Therefore, the claims as amended are novel over Nemphos.

c. U.S. Patent No. 5,753,782 to Hammond et al.

Hammond describes polyester compositions comprising a biodegradable polyester and a plasticizing quantity of at least one plasticizer selected from the group consisting of high boiling esters of polybasic acids, phosphoric acid derivatives, phosphorous acid derivatives, phosphonic acid derivatives, substituted fatty acids, high boiling glycols, polyglycols, polyoxyalkylenes, and

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glycerol (abstract). Hammond describes extruding compositions containing PHBV and a nucleant to form a single lace, which is dried and cut into granules. The granules are injection molded into dumbbell shaped tensile bars (Examples 1-3). Hammond does not disclose a method of making *blown or cast free-standing films* comprising melting a composition comprising a PHA and a thermal stabilizer, wherein the PHA in the film has a molecular weight greater than 456,000. The claims, as amended, are novel over Hammond.

d. U.S. Patent No. 5,061,743 to Herring et al.

Herring discloses PHA compositions comprising a PHA and a nucleating agent composed of a combination of an organophosphonic or organophosphoric acid or ester with an oxide, hydroxide, or carboxylate of a metal of Group I to V. Examples 1-4 describe extruding HB polymers containing varying amounts of HV monomer. Example 5 describes injection molding a formulation containing HB polymer containing 17% HV monomer. Herring does not disclose a *blown or cast free-standing film* comprising a PHA and a thermal stabilizer, *wherein the PHA in the film has a molecular weight greater than 456,000*. Therefore, the claims, as amended, are novel over Herring.

Rejection Under 35 U.S.C. § 103

Claims 66-73, 76, 78-89, 92, 94-111, 114, and 116-127 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,061,743 to Herring *et al.* ("Herring"), in view of U.S. Patent No. 5,502,273 to Bright *et al.* ("Bright") or U.S. Patent No. 5,753,782 to

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Hammond *et al.* ("Hammond") further in view of McBride or Nemphos. Applicants respectfully traverse this rejection to the extent that it is applied to the claims as amended.

The Legal Standard

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

"There are three possible sources for a motivation to combine references: the nature of the problem to be solved, the teachings of the prior art, and the knowledge of persons of ordinary skill in the art." *In re Rouffet*, 149 F.3d 1350, 1357, 47 USPQ2d 1453, 1457-58 (Fed. Cir. 1998) (The combination of the references taught every element of the claimed invention, however without a motivation to combine, a rejection based on a *prima facie* case of obvious was held improper.). The level of skill in the art cannot be relied upon to provide the suggestion to combine references. *Al-Site Corp. v. VSI Int'l Inc.*, 174 F.3d 1308, 50 USPQ2d 1161 (Fed. Cir. 1999).

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To establish prima facie obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. In re Royka, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). "All words in a claim must be considered in judging the patentability of that claim against the prior art." In re Wilson, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. In re Fine, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988).

Claims 66-73, 76, 78-89, 94, and 116-124 are canceled. Claims 95-101 are amended to recite a blown or cast free-standing film comprising a polyhydroxyalkanoate (PHA), wherein the PHA has a molecular weight greater than 456,000 and wherein the film is made by melting a pellet composition comprising the PHA and a thermal stabilizer. Claims 102-111 and 114 are amended to recite a method of producing a blown or cast *free-standing* film comprising melting a pellet composition comprising a PHA and a thermal stabilizer, wherein the PHA in the film has a molecular weight greater than 456,000.

a. U.S. Patent No. 5,061,743 to Herring et al.

As discussed above, Herring does not disclose or even suggest a blown or cast free-standing film comprising a PHA and a thermal stabilizer, wherein the PHA in the film has a molecular weight greater than 456,000 nor methods of making thereof. Herring is concerned with the use of nucleants to increase the rate of crystallization. Herring does not disclose or even suggest the use of a thermal stabilizer to inhibit the thermal degradation of the polymer compositions during film formation.

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AMENDMENT AND RESPONSE TO OFFICE ACTION***b. U.S. Patent No. 5,502,273 to Bright et al.***

Bright discloses a plant having a recombinant genome which contains or more of the genes specifying enzymes critical to the polyhydroxyalkanoate biosynthetic pathway, which produces polyhydroxyalkanoate polymer. Bright does not disclose or even suggest a blown or cast free-standing film comprising a PHA and a thermal stabilizer, wherein the PHA in the film has a molecular weight greater than 456,000 nor methods of making thereof.

c. U.S. Patent No. 5,753,782 to Hammond et al.

As discussed above, Hammond does not disclose or even suggest a blown or cast free-standing film comprising a PHA and a thermal stabilizer, wherein the PHA in the film has a molecular weight greater than 456,000 nor methods of making thereof.

d. U.S. Patent No. 5,217,803 to McBride et al.

As discussed above, McBride does not disclose or even suggest a blown or cast free-standing film comprising a PHA and a thermal stabilizer, wherein the PHA in the film has a molecular weight greater than 456,000 nor methods of making thereof.

e. U.S. Patent No. 5,300,576 to Nemphos et al.

As discussed above, Nemphos does not disclose a blown or cast free-standing film comprising a PHA and a thermal stabilizer, wherein the PHA in the film has a molecular weight greater than 456,000 nor methods of making thereof.

One of ordinary skill in the art would not be motivated to modify the references as required to produce the claimed methods, nor if one did combine the references, would one

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arrive at the claimed methods. Therefore, the claims, as amended, are not obvious over Herring in view of Bright or Hammond further in view of McBride or Nemphos.

Double Patenting Rejection

Claims 66-127 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-50 of U.S. Patent No. 6, 620,869 to Asrar *et al.* ("Asrar"). In response, and solely to facilitate prosecution, Applicant submits a terminal disclaimer to overcome the double patenting rejection.

Allowance of claims 95-115 and 125-135 is respectfully solicited.

Respectfully submitted,



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